MAY 11 2004

K032747

II. 510(K) Summary of Safety and Effectiveness Information

(Per 21 CFR 807.92)

1. **Submitter:** BIOTOP Technology Co., Ltd.
12F, No. 130, Chung-Hsiao E. Rd. Sec. 2
Taipei 100 Taiwan

Contact Person: Dr. Ke-Min Jen
Official Correspondent
886-3-5208829 (Tel)
886-3-5209783 (Fax)

2. **Date Prepared:** 2003/6/13

3. **Device Name:**

-Proprietary Name: BIOTOP DJT-A Safety Syringe

-Common Name: Sharps Injury Prevention Piston Syringe

-Classification Name: Antistick Syringe (MEG)

4. **Predicate Device:**

Claim of Substantial Equivalence (SE) is made to M.K. Meditech Company's DuoPro Safety Syringe (DuoProSS™) (K020623, K022806).

5. **Device Description:**

The BIOTOP DJT-A Safety Syringe is a single-use hypodermic syringe that is very similar to a traditional syringe, except it possesses an integral needle retracting mechanism. Upon employing traditional syringe injection techniques, the needle can be manually retracted back inside the syringe barrel.

6. **Intended Use:**

The BIOTOP DJT-A Safety Syringe serves as the vehicle in which medication can be injected into the human body, or fluid withdrawn from the human body, via the hypodermic needle injection. The safety mechanism may limit accidental needlestick injuries as well as help to prohibit syringe reuse.

7. Substantial Equivalence (SE) and Safety and Effectiveness Information:

BIOTOP Technology Co., Ltd. makes a Substantial Equivalence claim of the DJT-A safety syringe to M.K. Meditech's DuoProSS™. The two safety syringes are similar with regards to parts, design, material, operating procedure, and intended use. The DJT-A and the DuoProSS™ both consist of a syringe barrel, syringe plunger, single lumen hypodermic needle and needle hub, and a retracting mechanism on the syringe plunger head and the needle hub. The DJT-A needle employs a luer-lock mechanism while the DuoProSS™ can be both luer-slip or luer-lock. The design of the two syringes is similar in most of its parts, appearing like a traditional syringe. The DJT-A and DuoProSS™ uses identical PP plastic, lubricant, and needle. Both safety syringes are sterile and aseptic by employing ethylene oxide (EO) as the sterilization technique. The difference between the two safety syringes is the needle retracting mechanism. Both use a special tip on the head of the syringe plunger to be tightly connected to the needle hub as to allow the whole hub and needle to be manually retracted back inside the plunger. The difference between the two is the shape of the connecting tip on the syringe plunger. The DJT-A uses a hook to connect to the needle hub while the DuoProSS™ uses a knob-shaped tip to connect to the needle hub. However, the operating instructions for both safety syringes are identical with regards to how the needle is retracted back into the syringe barrel. Performed bench testing revealed similar performance data, under all conditions and stress. In addition, simulated field test suggests that the DJT-A is as safe and effective in its performance as the DuoProSS™. Therefore, no new safety and effectiveness concerns need to be raised. In addition, both syringes share identical purposes in its intended use. The DJT-A and the DuoProSS™ single-use safety syringes both intend to limit disease transmission through accidental needlestick injuries and through syringe reuse.

8. Performance Testing:

Bench, biocompatibility, sterility, substantial equivalence, and simulated clinical testing are employed upon submission of this 510(K) premarket notification according to the *Supplementary Guidance on Premarket Notification for Medical Devices with Sharps Injury Prevention Features; Guidance for Industry and FDA* document provided by CDRH/ FDA.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 11 2004

ROC Chinese-European Industrial Research Society
C/O Dr. Ke-Min Jen
Official Correspondent
Biotop Technology Company Limited
58 Fu-Chiun Street
Hsin Chu City,
CHINA (TAIWAN) 300

Re: K032747
Trade/Device Name: BIOTOP DJT-A Safety Syringe (3cc/mL)
Regulation Number: 880.5860
Regulation Name: Piston Syringe
Regulatory Class: II
Product Code: MEG
Dated: February 12, 2004
Received: February 20, 2004

Dear Dr. Jen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

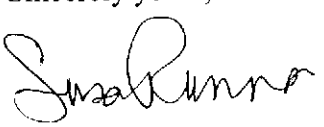
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4618. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address

Sincerely yours,



for Chiu Lin, Ph.D
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

IV. Indications for Use Statement

Applicant: BIOTOP TECHNOLOGY CO., LTD.

510(k) Number: **K032747**

Device Name: BIOTOP DJT-A Safety Syringe (3cc/mL)

Indications for Use:

The BIOTOP DJT-A Safety Syringe (3cc/mL) serves as the vehicle in which medication can be injected into the human body, or fluid withdrawn from the human body, via the hypodermic needle injection. The safety mechanism may limit accidental needle stick injuries as well as help to prohibit syringe reuse.

Prescription Use √	AND/OR	Over-The-Counter Use
(Part 21 CFR 801 Subpart D)		(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K032747